IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
SOUTHERN DIVISION

NO. 7:08-CV-130-FL

VICTOR BROWN Plaintiff, v. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	)	ORDER

With reference to matters still at issue concerning the testimony of Dr. Suzanne Parisian, anticipated to be presented by plaintiff this date, after extensive briefing and hearing, the court makes the following determinations:

1. At the outset, where plaintiff has not presented to the court an applicable regulation that uses the terminology "causal association," Dr. Parisian shall not use such terminology. It would only confuse the jury.

2. Dr. Parisian may **not** testify as to general or specific causation.

3. Dr. Parisian **may** testify as to what the applicable Federal Regulations required of drug manufacturers at various stages of the drug approval process.

4. Dr. Parisian **may** testify as to what constitutes "reasonable evidence of an association of a serious hazard with a drug," 21 C.F.R. § 201.57(e) (2005); see also 21 C.F.R. § 201.80(e); and more specifically as to whether there was such reasonable evidence in this case, subject to further limitations set forth below.

5. Dr. Parisian **may** testify that the applicable Federal Regulations required defendant to take particular action when it received particular material or information, **only to the extent** she is qualified by her training as a doctor of medicine, her FDA experience, consulting experience, and her review of materials in this litigation, to give such an opinion. Fed. R. Evid. 702.

6. Dr. Parisian may not attempt to provide opinion that requires expertise she does not possess, such as in the areas of oncology, dentistry, oral surgery, or bone disorders.

7. Specific examples raised at the 9/14/12 Daubert hearing and elsewhere in the record:

   a. "Summary of ONJ Cases in Zometa and Aredia Clinical Trials" (chart of 6 cases)[1]

      i. Dr. Parisian **may** testify as to what action, if any, the Federal Regulations required defendant to take when each diagnosis in the chart was made;

      ii. Dr. Parisian **may** testify as to what action, if any, the Federal Regulations required defendant to take in or around January 2005, when defendant in conducting its review of the Zometa and Aredia clinical trials recognized these 6 clinical trial results as possible cases of ONJ; but

      iii. Dr. Parisian may **not** testify that the six cases listed in this chart were actually cases of ONJ, where she testified at her Daubert hearing that it is not her testimony that any of these cases on the table are actual ONJ cases.[2]

   b. Gotcher & Jee, "The progress of the periodontal syndrome in the rice rat" (1981).

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[1] See 9/14/12 Hr. Tr. 50:13.

[2] See 9/14/12 Hr. Tr. 51:9 - 17 ("Q. Doctor, is it your testimony that any of these -- any of these cases on the table that's in front of you are actual osteonecrosis of the jaw cases. A. No, it hasn't been.").

i. Dr. Parisian **may** testify as to what action defendant should have taken, under the applicable Federal Regulations, due to the existence of the Gotcher & Jee article.

SO ORDERED, this the 20th day of September, 2012.

LOUISE W. FLANAGAN
United States District Judge